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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/664,871	09/19/2000	Francois Mach	EGYP 3.0-009	5326

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EXAMINER
HUI, SAN MING R

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 08/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/664,871	MACH, FRANCOIS	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *12,14, 33,34,38 and 39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,13,15-32 and 35-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election without traverse of the invention of Group I, claims 1-32 and 35-39 in Paper No. 9, received January 2, 2002 is acknowledged.

Applicant's further election without traverse of the specie of active as atorvastatin and the disorder specie as rheumatoid arthritis in Paper No. 9, received January 2, 2002 is acknowledged.

Claims 33-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9, received January 2, 2002.

Claims 12, 14, 38, and 39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected specie, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9, received January 2, 2002. Claim 14 recites a statin which does not have lipid-lowering effect. Atorvastatin is well-known to have lipid-lowering effect.

Claims 1-39 are pending.

Claims 1-11, 13, 15-32, and 35-37 have been examined herein to the extent they read on the elected invention and species.

Claim Objections

Claims 7, 21, 26, 27, 29, and 32 are objected to because of the following informalities: The use of the abbreviation "CIITA" is improper. Appropriate correction is required.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-8, 10, 11, 13, 15-20, and 35-37 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-7, 9-11, 13-16, 18, 20-26, and 31-33 of copending Application No. 09/960471. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The CD40-mediated anti-immuno-inflammatory effect in a mammal is inherently present in the method of administering a statin compound to the mammal.

Claims 2-8, 10-11, 13, 15-20, and 35-37 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 2-7, 9-11, 13-16, 18, 20-26, and 31-33 of copending Application No. 10/056608, 10/056288, 10/056,645, 10/056,133, and 10/056,606. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The CD40-mediated anti-immuno-inflammatory effect in a mammal is inherently present in the method of administering a statin compound to the mammal.

Claims 1-8, 10-11, 13, 15-20, and 35-37 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-7, 9-11, 13-16, 18, 20-26, and 31-33 of copending Application No.10/056,646. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The CD40-mediated anti-immuno-inflammatory effect in a mammal is inherently present in the method of administering a statin compound to the mammal.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11, 13, 15-32, and 35-37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 36-48 and 76-93 of U.S. Patent No. 10/056608, 10/056288, 10/056,645, 10/056,133, and 10/056,606. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the copending applications are drawn to a treatment of inflammatory conditions including rheumatoid arthritis. The only

difference is that the claims in the co-pending applications recite the employment of additional anti-rheumatoid agents. One of ordinary skill in the art would have been reasonably expected to employ additional anti-rheumatoid agents to treat inflammation such as rheumatoid arthritis because combining two agents which are known to be useful to treat rheumatoid arthritis individually into a single composition useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069.

Claims 1-11, 13, 15-32, and 35-37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 36-48 and 76-106 of U.S. Patent No. 10/056,646. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the copending applications are drawn to a treatment of inflammatory conditions including rheumatoid arthritis. The only difference is that the claims in the co-pending applications recite the employment of additional anti-rheumatoid agents. One of ordinary skill in the art would have been reasonably expected to employ additional anti-rheumatoid agents to treat inflammation such as rheumatoid arthritis because combining two agents which are known to be useful to treat rheumatoid arthritis individually into a single composition useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11, 13, 15-32, and 35-37 are rejected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

Applicant fails to set forth the criteria that defines a "functionally equivalent molecule of a statin". Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of "functionally equivalent molecule a statin"

examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all "functionally equivalent molecule", necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11, 13, 15-32, and 35-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "mammal in need of such treatment" in claim 1 renders the claims indefinite as to the patient population encompassed thereby.

The term "statin" in claim 1, for example, and throughout the application renders the claims indefinite as to what compounds are encompassed by the claims. It is not clear what naturally occurring and synthetic molecules in the statin Family are encompassed by the claims herein (See the specification, page 8, last paragraph). It is not clear what statin family is referred to in the instant case. Only a few well-known HMG-CoA reductase inhibitors are listed in the instant specification (See the specification, page 8, last paragraph). It is unclear to one of ordinary skill in the art

what other compounds are considered as "statin" compounds since a vast number of compounds would have been encompassed herein.

The term "IFN-γ responsive cell" in claim 21 renders the claims indefinite as to the patient population encompassed thereby. It is unclear what cell types, other then the cell types recited in claim 25, are encompassed by the claims. In the instant specification, page 9, line 18-23, applicant attempts to define what "IFN-γ responsive cell" is; however, the definition is merely a functional definition without expressly disclose what cell types are considered as "IFN-γ responsive cell".

The expression "a compound ... therapeutically insignificant lipid-lowering effect" in claim 36 renders the claim indefinite because it is not clear what HMG-CoA reductase inhibitors are encompassed by the claim. Atorvastatin is a well-known HMG-CoA reductase inhibitor that has lipid-lowering effect (See the instant specification, page 1, line 8-18). Is Atorvastatin encompassed by the claim then?

The term "therapeutically insignificant lipid-lowering effect" in claim 36 is a relative term which renders the claim indefinite. The term "therapeutically insignificant lipid-lowering effect" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear what lipid-lowering effect would be encompassed by the claims herein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-3, 6-7, 11, 13,15, and 20-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Partridge (US Patent 6,403,637 B1).

Partridge teaches a method of treating arthritis in a mammal comprising administering an effective amount of atorvastatin to the mammal (See particularly claims 1-13).

Applicants' attention is directed to *Ex parte Novitski*, 26 USPQ2d 1389 (BOPA 1993) illustrating anticipation resulting from inherent use, absent a *haec verba* recitation for such utility. In the instant application, as in *Ex parte Novitski*, supra, the claims herein are directed to achieving MHC Class II immunomodulation with old and well known compounds or compositions and the specific activities of the administration of an old and well known compound, atorvastatin, in cellular level. It is now well settled law that administering compounds inherently possessing a protective utility anticipates

claims directed to such protective use. Arguments that such protective use is not set forth *haec verba* are not probative. Prior use for the same utility clearly anticipates such utility, absent limitations distancing the proffered claims from the inherent anticipated use. Attempts to distance claims from anticipated utilities with specification limitations will not be successful. At page 1391, *Ex parte Novitski*, supra, the Board said "We are mindful that, during the patent examination, pending claims must be interpreted as broadly as their terms reasonably allow. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). As often stated by the CCPA, "we will not read into claims in pending applications limitations from the specification." *In re Winkhaus*, 52 F.2d 637, 188 USPQ 219 (CCPA 1975).". In the instant application, Applicants' failure to distance the proffered claims from the anticipated prophylactic utility, renders such claims anticipated by the prior inherent use.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4, 5, 8-10, 16-19, and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Partridge (US Patent 6,403,637 B1).

Partridge teaches a method of treating arthritis, including rheumatoid arthritis, in a mammal comprising administering an effective amount of atorvastatin to the mammal

(See particularly claims 1-13; also col. 6, line 19). Partridge also teaches the specific dosage and the route of administration of atorvastatin may be calculated depending on the formulation and route of administration of the compound (See col. 9, lines 40-62).

Partridge does not expressly teach that the mammal as human or a mammal not suffering from hypercholesterolemia. Partridge does not expressly teach the condition to be treated as rheumatoid arthritis. Partridge does not expressly teach the mammal being prepared for organ transplantation. Partridge does not expressly teach the dosage of atorvastatin as 10 – 80 mg daily or 20-40mg daily. Partridge does not expressly teach the route of administration as intralesional, intraperitoneal, in tramuscular or intravenous injection; infusion; or topical, nasal, oral, ocular or otic route of administration.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ atorvastatin, in the dosage and regimen herein, to treat rheumatoid arthritis in mammal who does not suffer from hypercholesterolemia or is being prepared for organ transplantation.

One of ordinary skill in the art would have been motivated to employ atorvastatin, in the dosage and regimen herein, to treat rheumatoid arthritis in mammal who does not suffer from hypercholesterolemia or is being prepared for organ transplantation because based on Partridge, atorvastatin is useful in treating arthritis. Therefore, one of ordinary skill in the art would have been reasonably expected atorvastatin to be useful in treating various forms of arthritis such as rheumatoid arthritis, regardless of the patient is: 1) suffering from hypercholesterolemia or 2) in preparation of organ transplatation, or not.

Moreover, the optimization of result therapeutic parameters (e.g., dosage range, dosing regimens) is obvious as being within the skill of the artisan. The skilled of artisan would possess all conventional administration methods for the active compounds such as oral administration. The selection of one or another route of administration would be seen as a simple selection from among obvious alternatives.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Russell Travers, J.D., can be reached on (703) 308-4603. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200

San-ming Hui
August 12, 2002